IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EPI HEALTH, LLC and ALLERGAN, INC.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	C.A. No. 19-1910 (CFC)
TARO PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	
	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs EPI Health, LLC ("EPI Health") and Allergan, Inc. ("Allergan") (EPI Health and Allergan, collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Taro Pharmaceuticals, Inc. ("Taro"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213584 submitted by Taro to the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 213584, Taro seeks approval to market an oxymetazoline cream product (the "Taro ANDA Product"), a generic version of RHOFADE® (oxymetazoline HCl) cream, 1%, prior to expiration of U.S. Patent Nos. 7,812,049 (the "'049 patent"); 8,420,688 (the "'688 patent"); 8,815,929 (the "'929 patent"); 9,974,773 (the "'773 patent"); and 10,335,391 (the "'391 patent"). The '049 patent, '688 patent, '929 patent, '773 patent, and '391 patent are collectively referred to herein as the "Patents-in-Suit."

PARTIES

3. Plaintiff EPI Health, LLC is a limited liability company organized and existing under the laws of South Carolina with its headquarters at 134 Columbus St., Charleston, South Carolina 29403.

4. EPI Health is a specialty pharmaceutical company focused on acquiring, developing and marketing prescription medical dermatological products. RHOFADE® is a product marketed by EPI Health for the treatment of persistent facial redness associated with rosacea. EPI Health sells RHOFADE® in this judicial district and throughout the United States.

5. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of Delaware with a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

6. Allergan is a global pharmaceutical leader focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical, and regenerative medicine products for patients around the world. Allergan brought RHOFADE® to the market in 2017.

7. On information and belief, Taro Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada.

JURISDICTION AND VENUE

8. This case arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq. This Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has jurisdiction over Taro because, *inter alia*, Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct

that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including Delaware corporation Allergan, in Delaware. For example, on information and belief, following approval of ANDA No. 213584, Taro will make, use, import, sell, and/or offer for sale the Taro ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

10. This Court also has jurisdiction over Taro because, *inter alia*, this action arises from actions of Taro directed toward Delaware, and because Taro has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Taro regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. On information and belief, Taro derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

11. Venue is proper against Taro in this District under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b), because venue in a patent infringement action against a foreign defendant is proper in any judicial district. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 n.2 (2017) (citing *Brunette Mach. Works, Ltd. v. Kochum Indus., Inc.*, 406 U.S. 706, 711-714 (1972)).

12. Taro, through its counsel, by e-mail dated September 25, 2019, agreed that Taro does not contest jurisdiction or venue in this Court for purposes of this case.

PATENTS-IN-SUIT

13. On October 12, 2010, the U.S. Patent and Trademark Office duly and legally issued the ’049 patent, titled “Method and Therapeutic/Cosmetic Topical Compositions for the

Treatment of Rosacea and Skin Erythema Using α_1-Adrenoceptor Agonists." A true and correct copy of the '049 patent is attached hereto as Exhibit A. The claims of the '049 patent are valid, enforceable, and not expired. Allergan is the owner of the '049 patent and EPI Health is the exclusive licensee of the '049 patent.

14. On April 16, 2013, the U.S. Patent and Trademark Office duly and legally issued the '688 patent, titled "Method and Therapeutic/Cosmetic Topical Compositions for the Treatment of Rosacea and Skin Erythema Using α_1-Adrenoceptor Agonists." A true and correct copy of the '688 patent is attached hereto as Exhibit B. The claims of the '688 patent are valid, enforceable, and not expired. Allergan is the owner of the '688 patent and EPI Health is the exclusive licensee of the '688 patent.

15. On August 26, 2014, the U.S. Patent and Trademark Office duly and legally issued the '929 patent, titled "Method and Therapeutic/Cosmetic Topical Compositions for the Treatment of Rosacea and Skin Erythema Using α_1-Adrenoceptor Agonists." A true and correct copy of the '929 patent is attached hereto as Exhibit C. The claims of the '929 patent are valid, enforceable, and not expired. Allergan is the owner of the '929 patent and EPI Health is the exclusive licensee of the '929 patent.

16. On May 22, 2018, the U.S. Patent and Trademark Office duly and legally issued the '773 patent, titled "Stabilized Oxymetazoline Formulations and Their Uses." A true and correct copy of the '773 patent is attached hereto as Exhibit D. The claims of the '773 patent are valid, enforceable, and not expired. EPI Health is the owner of the '773 patent.

17. On July 2, 2019, the U.S. Patent and Trademark Office duly and legally issued the '391 patent, titled "Stabilized Oxymetazoline Formulations and Their Uses." A true and correct

copy of the '391 patent is attached hereto as Exhibit E. The claims of the '391 patent are valid, enforceable, and not expired. EPI Health is the owner of the '391 patent.

18. EPI Health is the holder of New Drug Application ("NDA") No. 208552, by which FDA granted approval for the marketing and sale of a 1% oxymetazoline hydrochloride cream. EPI Health markets 1% oxymetazoline hydrochloride cream in the United States, under the trade name "RHOFADE®." The FDA's official publication of approved drugs, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Patents-in-Suit for RHOFADE®.

19. The active ingredient of RHOFADE® is an $alpha_{1A}$ adrenoceptor agonist used on the skin (topically) of the face to treat persistent facial redness, also referred to as erythema, associated with rosacea in adults. RHOFADE® is a vasoconstrictor and works by constricting facial blood vessels to reduce facial redness associated with rosacea.

20. The prescribing information for RHOFADE® identifies the product as including "an $alpha_{1A}$ adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults."

INFRINGEMENT BY TARO

21. By a letter dated August 28, 2019, Taro notified Allergan and Aclaris Therapeutics, Inc. that Taro had submitted ANDA No. 213584 to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "Rhofade Notice Letter").

22. The Rhofade Notice Letter states that Taro has submitted ANDA No. 213584 under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, importation, offer for sale, or sale of the Taro ANDA Product before the expiration of the Patents-in-Suit. On

information and belief, Taro intends to—directly or indirectly—engage in the commercial manufacture, use, importation, and/or sale of the Taro ANDA Product.

23. By submitting ANDA No. 213584 to the FDA, Taro has necessarily represented to the FDA that the Taro ANDA Product has the same active ingredient as RHOFADE®, has the same dosage form and strength as RHOFADE®, and is bioequivalent to RHOFADE®.

24. On information and belief, Taro is seeking approval to market the Taro ANDA Product for the same approved indication as RHOFADE®.

25. On information and belief, ANDA No. 213584 includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

26. On information and belief, the proposed package insert for the Taro ANDA Product will include the same active ingredient, dosage strength, dosage form, and labeling (including condition of use and dosing) as RHOFADE®, including an active ingredient of oxymetazoline, a dosage strength of 1%, a dosage form of a topical cream, and an indication for the topical treatment of persistent facial erythema associated with rosacea in adults with a once-daily dose.

27. In the Rhofade Notice Letter, Taro alleged that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Taro ANDA Product.

28. Taro offered confidential access to portions of its ANDA No. 213584, on terms and conditions set forth in the Rhofade Notice Letter ("the Taro Offer"). Taro requested that Allergan and Aclaris accept the Taro Offer before receiving access to Taro's ANDA No. 213584. The Taro Offer contained unreasonable restrictions well beyond those that would apply under a

protective order on who could view the ANDA. For example, the Taro Offer contained a broad patent prosecution bar, which, among other things, does not have a carve out for *inter partes* reviews, and a broad bar on any work related to actions before FDA. The Taro Offer unreasonably restricted the ability of counsel to seek the opinions of Allergan's and Aclaris' employees and outside experts. The Taro offer also unreasonably would have prevented Plaintiffs from incorporating and relying on confidential information in this Complaint. The restrictions Taro has placed on access to ANDA No. 213584 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

29. On October 8, 2019, Aclaris Therapeutics, Inc. ("Aclaris") and Allergan brought this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Rhofade Notice Letter. *See* 21 U.S.C. § 355(c)(3)(C).

30. On or about October 10, 2019, Aclaris conveyed all of its rights to NDA No. 208552 and the Patents-in-Suit to EPI Health.

31. Through a stipulation by all parties so-ordered by the Court, EPI Health was substituted for Aclaris as Plaintiff in this action.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,812,049

32. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth herein.

33. Taro's submission of ANDA No. 213584 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of the Taro ANDA Product prior

to the expiration of the ’049 patent constituted a technical act of infringement of at least one claim of the ’049 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(e)(2)(A). In the Rhofade Notice Letter, Taro has not contested the infringement of any claim of the ’049 patent.

34. Taro’s commercial manufacture, use, offer to sell, sale, or importation of the Taro ANDA Product prior to the expiration of the ’049 patent, and/or its inducement of or contribution to such conduct, would further infringe at least one claim of the ’049 patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (c).

35. Upon FDA approval of Taro’s ANDA No. 213584, Taro will infringe one or more claims of the ’049 patent, including at least claim 1, by making, using, offering to sell, and selling the Taro ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the ’049 patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

36. On information and belief, Taro specifically intends to actively induce infringement by others of one or more claims of the ’049 patent. On information and belief, Taro has filed an ANDA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

37. On information and belief, the proposed package insert includes that the Taro ANDA Product is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults, the active ingredient in Taro’s ANDA Product is oxymetazoline, its dosage strength is 1%, and its proposed dosage form is a topical cream. On information and belief, the

proposed package insert for the Taro ANDA Product includes information indicating that the Taro ANDA Product will effectively decrease erythema resulting from rosacea.

38. On information and belief, Taro is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Taro ANDA Product at least according to Taro's proposed package insert and, therefore, will directly infringe at least one claim of the '049 patent.

39. On information and belief, Taro will knowingly or with willful blindness induce another's direct infringement of at least one claim of the '049 patent, by at least Taro's proposed package insert for the Taro ANDA Product.

40. On information and belief, Taro knows that the Taro ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '049 patent, and that the Taro ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Taro plans and intends to, and will contribute to the infringement of the '049 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 213584.

41. Taro has knowledge of and is aware of the '049 patent, including due to RHOFADE®'s Orange Book entry listing the Patents-in-Suit and the filing of this Complaint.

42. If Taro's marketing and sale of the Taro ANDA Product prior to expiration of the '049 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 8,420,688

43. Each of the preceding paragraphs 1 to 42 is incorporated as if fully set forth herein.

44. Taro's submission of ANDA No. 213584 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of the Taro ANDA Product prior to the expiration of the '688 patent constituted a technical act of infringement of at least one claim of the '688 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(e)(2)(A). In the Rhofade Notice Letter, Taro has not contested the infringement of any claim of the '688 patent.

45. Taro's commercial manufacture, use, offer to sell, sale, or importation of the Taro ANDA Product prior to the expiration of the '688 patent, and/or its inducement of or contribution to such conduct, would further infringe at least one claim of the '688 patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (c).

46. Upon FDA approval of Taro's ANDA No. 213584, Taro will infringe one or more claims of the '688 patent, including at least claim 1, by making, using, offering to sell, and selling the Taro ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '688 patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

47. On information and belief, Taro specifically intends to actively induce infringement by others of one or more claims of the '688 patent. On information and belief, Taro has filed an ANDA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

48. On information and belief, the proposed package insert includes that the Taro ANDA Product is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults, the active ingredient in Taro's ANDA Product is oxymetazoline, its dosage strength is 1%, and its proposed dosage form is a topical cream. On information and belief, Taro is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Taro ANDA Product at least according to Taro's proposed package insert and, therefore, will directly infringe at least one claim of the '688 patent.

49. On information and belief, Taro will knowingly or with willful blindness induce another's direct infringement of at least one claim of the '688 patent, by at least Taro's proposed package insert for the Taro ANDA Product.

50. On information and belief, Taro knows that the Taro ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '688 patent, and that the Taro ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Taro plans and intends to, and will contribute to the infringement of the '688 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 213584.

51. Taro has knowledge of and is aware of the '688 patent, including due to RHOFADE®'s Orange Book entry listing the Patents-in-Suit and the filing of this Complaint.

52. If Taro's marketing and sale of the Taro ANDA Product prior to expiration of the '688 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 8,815,929

53. Each of the preceding paragraphs 1 to 52 is incorporated as if fully set forth herein.

54. Taro's submission of ANDA No. 213584 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of the Taro ANDA Product prior to the expiration of the '929 patent constituted a technical act of infringement of at least one claim of the '929 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(e)(2)(A). In the Rhofade Notice Letter, Taro has not contested the infringement of any claim of the '929 patent.

55. Taro's commercial manufacture, use, offer to sell, sale, or importation of the Taro ANDA Product prior to the expiration of the '929 patent, and/or its inducement of or contribution to such conduct, would further infringe at least one claim of the '929 patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (c).

56. Upon FDA approval of Taro's ANDA No. 213584, Taro will infringe one or more claims of the '929 patent, including at least claim 1, by making, using, offering to sell, and selling the Taro ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '929 patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

57. On information and belief, Taro specifically intends to actively induce infringement by others of one or more claims of the '929 patent. On information and belief, Taro has filed an ANDA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

58. On information and belief, the proposed package insert includes that the Taro ANDA Product is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults, the active ingredient in Taro's ANDA Product is oxymetazoline, its dosage strength is 1%, and its proposed dosage form is a topical cream.

59. On information and belief, Taro is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Taro ANDA Product at least according to Taro's proposed package insert and, therefore, will directly infringe at least one claim of the '929 patent.

60. On information and belief, Taro will knowingly or with willful blindness induce another's direct infringement of at least one claim of the '929 patent, by at least Taro's proposed package insert for the Taro ANDA Product.

61. On information and belief, Taro knows that the Taro ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '929 patent, and that the Taro ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Taro plans and intends to, and will contribute to the infringement of the '929 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 213584.

62. Taro has knowledge of and is aware of the '929 patent, including due to RHOFADE®'s Orange Book entry listing the Patents-in-Suit and the filing of this Complaint.

63. If Taro's marketing and sale of the Taro ANDA Product prior to expiration of the '929 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 9,974,773

64. Each of the preceding paragraphs 1 to 63 is incorporated as if fully set forth herein.

65. Taro's submission of ANDA No. 213584 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of the Taro ANDA Product prior to the expiration of the '773 patent constituted a technical act of infringement of at least one claim of the '773 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(e)(2)(A). In the Rhofade Notice Letter, Taro has not contested the infringement of any claim of the '773 patent.

66. Taro's commercial manufacture, use, offer to sell, sale, or importation of the Taro ANDA Product prior to the expiration of the '773 patent, and/or its inducement of or contribution to such conduct, would further infringe at least one claim of the '773 patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (c).

67. Upon FDA approval of Taro's ANDA No. 213584, Taro will infringe one or more claims of the '773 patent, including at least claim 1, by making, using, offering to sell, and selling the Taro ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '773 patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

68. On information and belief, Taro specifically intends to actively induce infringement by others of one or more claims of the '773 patent. On information and belief, Taro has filed an ANDA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

69. On information and belief, the proposed package insert includes that the Taro ANDA Product is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults, the active ingredient in Taro's ANDA Product is oxymetazoline, its dosage strength is 1%, the Taro ANDA product should be administered once daily on the face, and that its proposed dosage form is a topical cream.

70. On information and belief, Taro is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Taro ANDA Product at least according to Taro's proposed package insert and, therefore, will directly infringe at least one claim of the '773 patent.

71. On information and belief, Taro will knowingly or with willful blindness induce another's direct infringement of at least one claim of the '773 patent, by at least Taro's proposed package insert for the Taro ANDA Product.

72. On information and belief, Taro knows that the Taro ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '773 patent, and that the Taro ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Taro plans and intends to, and will contribute to the infringement of the '773 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 213584.

73. Taro has knowledge of and is aware of the '773 patent, including due to RHOFADE®'s Orange Book entry listing the Patents-in-Suit and the filing of this Complaint.

74. If Taro's marketing and sale of the Taro ANDA Product prior to expiration of the '773 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V

INFRINGEMENT OF U.S. PATENT NO. 10,335,391

75. Each of the preceding paragraphs 1 to 74 is incorporated as if fully set forth herein.

76. Taro's submission of ANDA No. 213584 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of the Taro ANDA Product prior to the expiration of the '391 patent constituted a technical act of infringement of at least one claim of the '391 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(e)(2)(A). In the Rhofade Notice Letter, Taro has not contested the infringement of any claim of the '391 patent.

77. Taro's commercial manufacture, use, offer to sell, sale, or importation of the Taro ANDA Product prior to the expiration of the '391 patent, and/or its inducement of or contribution to such conduct, would further infringe at least one claim of the '391 patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (c).

78. Upon FDA approval of Taro's ANDA No. 213584, Taro will infringe one or more claims of the '391 patent, including at least claim 1, by making, using, offering to sell, and selling the Taro ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '391 patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

79. On information and belief, Taro specifically intends to actively induce infringement by others of one or more claims of the '391 patent. On information and belief, Taro has filed an ANDA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Taro ANDA Product.

80. On information and belief, the proposed package insert includes that the Taro ANDA Product is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults, the active ingredient in Taro's ANDA Product is oxymetazoline, its dosage strength is 1%, the Taro ANDA product should be administered once daily on the face, and that its proposed dosage form is a topical cream. On information and belief, the proposed package insert for the Taro ANDA Product includes information indicating that patients administered the Taro ANDA Product will not experience rebound or worsening of facial erythema post-treatment.

81. On information and belief, Taro is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Taro ANDA Product at least according to Taro's proposed package insert and, therefore, will directly infringe at least one claim of the '391 patent.

82. On information and belief, Taro will knowingly or with willful blindness induce another's direct infringement of at least one claim of the '391 patent, by at least Taro's proposed package insert for the Taro ANDA Product.

83. On information and belief, Taro knows that the Taro ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '391 patent, and that the Taro ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Taro plans and intends to, and will contribute to the infringement of the '391 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 213584.

84. Taro has knowledge of and is aware of the '391 patent, including due to RHOFADE®'s Orange Book entry listing the Patents-in-Suit and the filing of this Complaint.

85. If Taro's marketing and sale of the Taro ANDA Product prior to expiration of the '391 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Taro and grant the following relief:

1. A judgment that the claims of the Patents-in-Suit are not invalid, are not unenforceable, and are infringed by Taro's submission of ANDA No. 213584 under 35 U.S.C. § 271(e)(2)(A), and that Taro's making, using, offering to sell, or selling in the United States, or importing into the United States the Taro ANDA Product will infringe the claims of the Patents-in-Suit under at least 35 U.S.C. §§ 271(b) and/or (c).

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 213584 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Taro, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Taro ANDA Product until after the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Taro engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Taro ANDA Product prior to the latest expiration

date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. A finding that this is an exceptional case and awarding Plaintiffs their reasonable attorneys' fees.

6. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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November 26, 2019

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 26, 2019, upon the following in the manner indicated:

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